Exhibit#1

MAY 1 3 2013

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: July 2, 2012

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
Tel: +41 79 216 0070
E-Mail: gerhard.frick@microlife.ch

2. Name of the Device:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model Cardio+ (BP4GAPO-2M)

Regulation Number: 21 CFR Part 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II
Product Code: DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

a. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3AC1-1 PC, K060686, Microlife Intellectual Property GmbH.

b. Fully Atuomatic Arm Cuff Electronic Blood Pressure Dock, K102939, Model iHealth BP3, ANDON HEALTH CO.,LTD

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model Cardio+ (BP4GAPO-2M) is designed to measure systolic and diastolic blood pressure, pulse rate of an individual by using a non-invasive technique in which one inflatable cuff is wrapped around the single upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but use two resistive pressure sensors rather than a stethoscope and mercury manometer. The sensors convert tiny alterations in cuff pressure to electrical signals, by analyzing those signals to

define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

The Cardio+ (BP4GAPO-2M) achieves its function by integrating the device with an iPhone, iPad, or iPod Touch. Because the device does not contain an LCD or other display components, it is necessary for the device to connect with an iPhone, iPad, or iPod Touch containing supporting software to constitute a complete blood pressure measure system.

In addition, the device can be used in connection with your personal computer **(PC)** running the software. The memory data can be transferred to the PC by connecting the monitor with the PC via cable.

5. Intended Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model Cardio+ (BP4GAPO-2M) is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual by using a non-invasive oscillometric technique in one inflatable cuff is wrapped around the single upper arm.

The Cardio+ (BP4GAPO-2M) achieves its function by integrate the device with an iPhone, iPad, or iPod.

The device can be used in connection with your personal computer (PC) running the software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The modified device Model Cardio+(BP4GAPO-2M) and the predicate device Model BP3AC1-1 PC use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff is inflated automatically, deflation rate is controlled by one factory set exhaust valve and the deflation pressures are transferred via tubing to one (or two) sensor(s).

The differences between the two models are appearance, sensor type, software analyzer, cuff and display way (the subject device must connect with an iPhone , iPad, or iPod Touch to display and achieve its function, but the predicate BP3AC1 -1 PC need not). However, the differences do not affect the accuracy and normal use of this device based on the documentation accompanying this submission. .

In addition, the modified device Model Cardio+ (BP4GAPO-2M) can achieve its function with an iPhone, iPad or iPod Touch, which is the same as with the predicate device, iHealth BP3, K102939.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model Cardio+(BP4GAPO-2M) in the intended environment of use is supported by testing that was conducted in

accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

a. Reliability Test - Storage test
b. Reliability Test - Operating test
c. Reliability Test - Vibration test
d. Reliability Test - Drop test
e. Reliability Test - Life test
f. EMC Test
g. IEC 60601-1 Safety Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model CARDIO+(BP4GAPO-2M) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

The subject modified device Model Cardio+ (BP4GAPO-2M) is, from the technical point of view, identical to the blood pressure monitor Model BP3AC1-1 PC. The differences between these two devices do not relate to blood pressure measurement technology. Therefore, the clinical accuracy in terms of blood pressure detection will not be affected. Based on this, repeated clinical testing in accordance with ANSI/AAMI SP10 is therefore not required.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". In addition, since our device requires the use of off-the-shelf software to operate the PC-link function, we adhered to the FDA September 1999 document "Guidance for Off-The-Shelf Software Use in Medical Devices".

10. Conclusions:

We have demonstrated that there are no significant differences between the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model Cardio+ (BP4GAPO-2M) and the predicate devices, Model BP3AC1-1 PC and Model iHealth BP3, in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and the ANSI/AAMI Voluntary Standard, SP10: 2008.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Microlife Intellectual Property GmbH
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K122013
Trade/Device Name: Microlife Upper Arm Digital Blood Pressure Monitor, Model Cardio+ (BP4GAPO-2M)
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: April 29, 2013
Received: April 30, 2013

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): ____K122013_____

Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model Cardio+（BP4GAPO-2M）

Indications For Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model Cardio+（BP4GAPO-2M）is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual by using a non-invasive oscillometric technique in one inflatable cuff is wrapped around the single upper arm.

The Cardio+（BP4GAPO-2M）achieves its function by integrating the device with an iPhone, iPad, or iPod Touch.

The device can be used in connection with your personal computer **(PC)** running the software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

Prescription Use _____ **AND/OR** **Over-The-Counter Use** _ X _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
2013.05.13
16:25:33 -04'00'